

Creating a Drug Listing SPL Document for a Product That Is Both a Cosmetic and a Drug

Basic instructions for creating a technically valid listing SPL document for a product that is both a cosmetic and a drug.

Version 1.1

Use SPL Starter Package

- Link to SPL Starter Package is located under the heading "Resources" on this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

***You can also utilize other SPL authoring software solutions to create valid SPL documents. See this web page: <http://spl-work-group.wikispaces.com/Vendors>

NOTE: This is NOT an FDA endorsement for these software products.

Accessing the Listing SPL Xforms

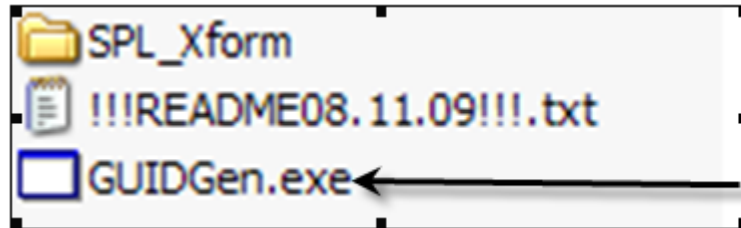
- Open listing SPL document Xforms file “SPLForm_DrugListing.xhtml” (or equivalent in your SPL authoring software.)

Selecting Document Type

The screenshot shows a software interface for creating documents. At the top, there are three buttons: 'Open', 'Save As', and 'Save'. Below these are four tabs: 'Document Information', 'Drug Listing', 'Content of Labeling', and 'Preview'. The 'Document Information' tab is currently selected. Within this tab, there is a section titled 'Document Information' which contains a label 'Type of document' and a dropdown menu. The dropdown menu is open, showing the selected option 'HUMAN OTC DRUG LABEL' and a small downward arrow icon on the right.

- Select “Human OTC Drug Label” from the drop-down menu.

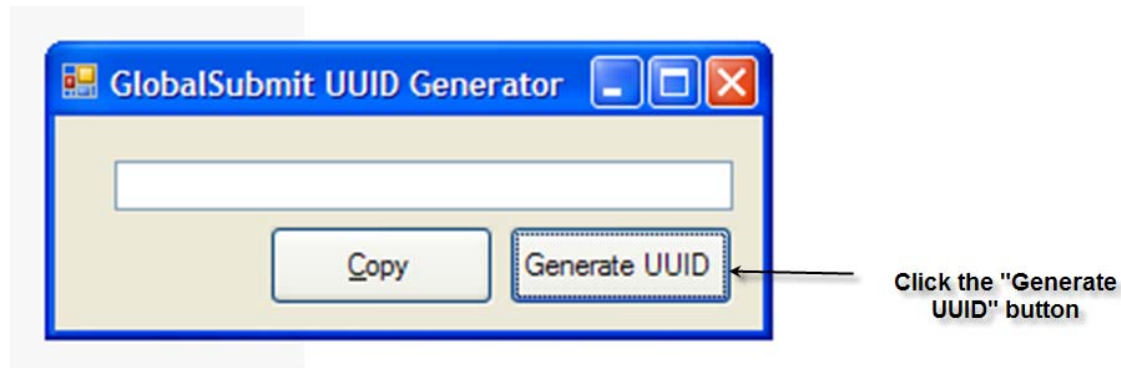
Generating GUIDs for IDs



Use the **GUID** generator executable file
or online version

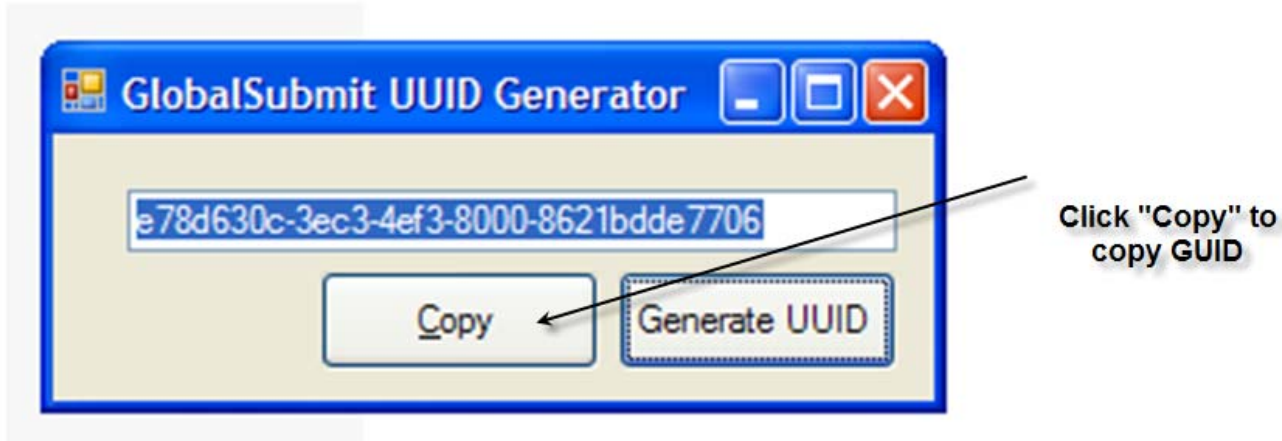
- Locate the Globally Unique Identifier (GUID) generator in the folder containing the SPL Xforms. GUIDs are also referred to as Universal Unique Identifiers (UUIDs)
- Double click executable file named “GUIDGen.exe.”
- If this program is incompatible with your PC, then search for an “online GUID generator” via your internet browser.

Generating GUIDs for IDs cont...



- Generate a GUID by choosing the “Generate UUID” button (or equivalent in online GUID generator tool.)

Generating GUIDs for IDs cont...



- Copy a GUID by choosing the “Copy” button (or equivalent in online GUID generator tool.)

Adding a SPL Document ID

ID

c46d775b-d995-4bc7-b3ac-e979c8c157aa

- Paste GUID in “ID” field
- The id root uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID).
- Hereafter, the “id root” will be referred to as “ID” or “document ID” in this eBook.

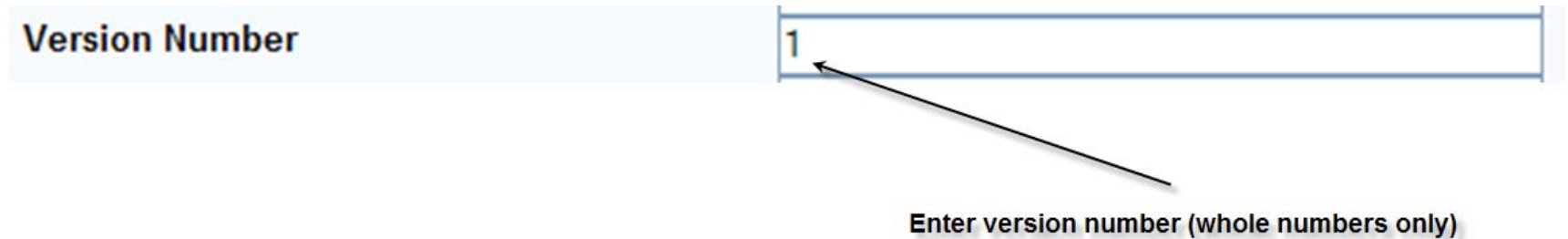
Assigning a Set ID

Set ID

c2ad48a4-85ca-47b7-bb66-f260802e8c88

- Generate and copy another GUID using the GUID generator.
- Paste this GUID in the “Set ID” field.
- The setID root uniquely identifies a group of versions of an SPL file.

Version Number



Version Number

1

Enter version number (whole numbers only)

- Enter a version number.
- The version number must be a **whole** number greater than zero.
- No spaces should be included before or after the version number.

Entering a Document Date

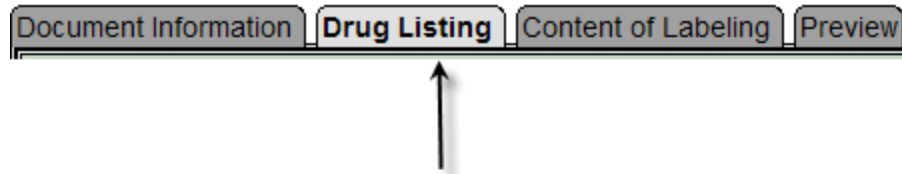
Effective Time	20090920
----------------	----------

Enter approximate submission date



- Enter a document date (Effective Time)
- Ensure that there are no spaces (created w/keyboard space bar) before or after date.
- The effective time provides a date reference to the SPL version. The date includes the year, month and day using the format yyymmdd.

Navigating to the Drug Listing Screen



Click the "Drug Listing" tab

- Now that you have entered the document tracking information, navigate to the drug listing screen by clicking the “Drug Listing” tab.

Entering the Labeler's Name

Labeler	
Name	<input type="text" value="Acme Cosmetics"/>

- Type in the name of the labeler.
- The labeler is the registrant or private label distributor (PLD) requesting the NDC Labeler Code or the registrant or PLD who is submitting an already assigned NDC Labeler Code.
- Ensure that the labeler name is the same as the name in the NDC Labeler Code SPL that has the labeler code which is the first segment of the NDC in this listing SPL.

Labeler's DUNS Number

Labeler	
Name	Acme Cosmetics
DUNS Number	855993211

Enter the DUNS Number for the Labeler

- Type the DUNS Number for the labeler code owner's headquarters.
- Ensure **no hyphens** are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number
- Ensure that the labeler DUNS Number is the same as the number in the NDC Labeler Code SPL which has the labeler code which is the first segment of the NDC in this listing SPL.


Registrant Listing for PLD Name

Registrant	
Name	Sunscreen, LLC

- The registrant (owner/operator) of establishments (which manufactured the product) name is included **IF** the registrant is listing a drug made for a private label distributor.
- Otherwise, **DO NOT** complete this field in the listing SPL.
- Use the business name of registrant.

Registrant Listing for PLD DUNS Number

Registrant	
Name	Sunscreen, LLC
DUNS number	491283147




Enter the DUNS Number for the registrant

- Type the DUNS Number for the registrant.
- **Only complete this field if you are the registrant listing on behalf of the PLD.**
- Ensure no hyphens are included in the DUNS Number.
- Do not include spaces (created w/space bar) before or after DUNS Number

Marking the Registrant As Confidential

Registrant	
Name	Sunscreen, LLC
DUNS number	491283147
Mark as Confidential	<input type="checkbox"/>



Check here if registrant's information is confidential

- Use checkbox if the registrant information is confidential.
- Information marked confidential will be redacted by FDA system prior to publication of data should information in this file be made public.


Adding Establishments to Listing File

Establishment	
Name	Sunscreen, LLC

- The establishments are the entities involved in the manufacturing or processing the product which is both a cosmetic and drug.
- Enter one or more establishments.

Entering DUNS Number for Establishment

Establishment	
Name	Sunscreen, LLC
DUNS number	491283147




Enter the DUNS Number for the establishment

- Type the DUNS Number for the establishment.
- Ensure **no hyphens** are included in the DUNS Number.
- Do not include spaces (created w/keyboard space bar) before or after DUNS Number

Marking Establishment As Confidential

Establishment	
Name	Sunscreen, LLC
DUNS number	491283147
Mark as Confidential	<input type="checkbox"/>



Check the box if the establishment information is confidential

- Check if the establishment information is confidential.
- Information marked confidential will be redacted by FDA system prior to publication of data should information in this file be made public.

Type of Operation for Establishment

Type of operation

manufacture

Add Type of Operation

Delete Type of Operation

To include additional types of operation, click the "Add Type of Operation" button.

Use drop-down list to select appropriate type of operation

- Select a type(s) of operation performed at the establishment for this specific drug product.
- Click the “Add Type of Operation” button to add **additional** operations. If no additional operations, ignore this button.

Additional Establishments



- To include additional drug establishments, click the “Add Establishment” button.
- To remove drug establishments, select “Delete Establishment”.

Add Product Data Elements Section



- Each drug listing SPL for a product which is both a cosmetic and a drug should have at least one product data elements section.
- Click the “Add Product” button

Product Data Elements Section ID

ID	e9612806-2469-4113-b5d2-dca534e4e145
----	--------------------------------------



Add an ID for product data element section


- Each section has an ID (GUID)
- Add the ID for product data element section.

Section's Effective Time (Date)

Effective Time	20090626
----------------	----------

- Enter a time stamp (effective time) for the section
- Ensure that there are no spaces (created w/space bar) before or after date.
- The effective time provides a date reference for the section.
- The date includes the year, month and day using the format yyyyymmdd.

Dosage Form

Product Information	
Dosage Form	CREAM 

- The dosage form of the drug product is the physical form as packaged.
- Select the appropriate dosage form from the drop down list.

Proprietary Name

Proprietary Name

Sundale

- The proprietary name is the brand or trade name **without additional qualifiers** such as “extra strength” or “XR”.
- For drug products which do not have a proprietary name, include the non proprietary name without additional qualifiers as the proprietary name.
- Enter the proprietary name. If there is a suffix, leave a space after the name.

Proprietary Name Suffix

Proprietary Name Suffix

- The proprietary name suffix is **the additional qualifiers** added to the proprietary name.
- If there are no additional qualifiers, then leave suffix field empty.

Non-proprietary Name

Non-Proprietary Name

Zinc Oxide

- Enter name(s) of active ingredient(s) in the non-proprietary name field in product data elements section.
- **DO NOT** include “USP” in the non-proprietary field in the product data elements section

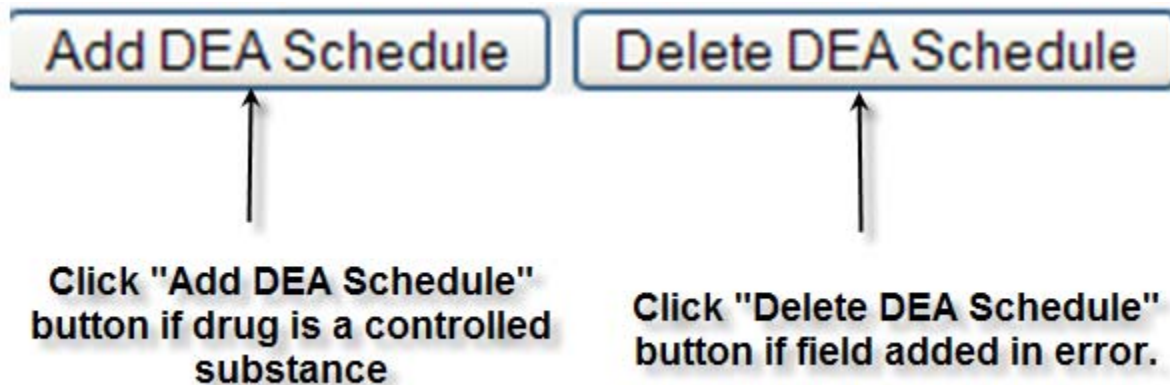
NDC Product Code

NDC Product Code

11445-123

- The NDC Product Code is the NDC Labeler Code and the product segment of the NDC separated by a hyphen.
- Enter the NDC Product Code

DEA Schedule



- Click “Add DEA Schedule” button, if applicable.
- From the drop-down menu, select the appropriate DEA schedule for the drug product

Route of Administration

Route of Administration	TOPICAL	▼
-------------------------	---------	---

- Click “Add Route of Administration” button
- Select the route of administration applicable for drug product.

Active Ingredients



- Click “Add Active Ingredient” button if there are active ingredients.
- Select “Delete Active Ingredient” button if chosen in error.
- Select “Add Active Ingredient” button for each active ingredient.


Active Ingredient Name

Active Ingredient	
Name	Zinc Oxide

- Enter active ingredient name (preferred name) without additional qualifiers such as “USP,” “NF,” etc...

Adding UNII for Active Ingredient

Active Ingredient	
Name	Zinc Oxide
Unique Ingredient Identifier (UNII)	SOI2LOH54Z




Enter UNII for active ingredient.

- Enter the preferred name and Unique Ingredient Identifier (UNII) for the active ingredient.
- Select UNIIs from list accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/Structure dProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.

Strength of Active Ingredient

Active Ingredient	
Name	Zinc Oxide
Unique Ingredient Identifier (UNII)	SOI2LOH54Z
Strength	223 mg in 1 g

Express strength as a ratio.
Use metric units



- Strength is represented as a ratio.
- The numerator and denominator have a value and a unit.
- The value is the amount of ingredient for a dose (usually a whole number) based on either the active ingredient or active moiety.
- Enter the value and select the appropriate unit for the numerator and denominator for the strength.

Active Moiety Name

Active Moiety


Name

Zinc Cation

- There are one or more active moieties for each active ingredient.

Entering UNII for Active Moiety

Active Moiety	
Name	Zinc Cation
Unique Ingredient Identifier (UNII)	13S1S8SF37
<input type="button" value="Add Active Moiety"/> <input type="button" value="Delete Active Moiety"/>	




Enter the UNII for the active moiety.

- Enter the preferred name and UNII for the active moiety for the active ingredient.
- Select UNII from list accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>
- If UNII is not in list, request UNII via e-mail to spl@fda.hhs.gov.
- Click “Add Active Moiety” button to include additional active moieties.


Basis of Strength

Basis of Strength

Active Ingredient 


- Select if the active ingredient or active moiety was used as the basis of the strength of the drug.

Marketing Status of Product

Marketing Date	
Product Status	Active 

- The marketing status describes the activity of the product.
- If the product is on the market, choose “Active.”
- If the product is no longer on the market, choose “Completed” as the marketing status.

Entering Marketing Start Date for a Currently Marketed Product

Marketing Date	
Product Status	Active 
Start Marketing Date	20080313

- If product is on the market, enter the approximate start marketing date using the YYYYMMDD format.

Entering Marketing End Date for a Discontinued Product

Marketing Date	
Product Status	Completed
Start Marketing Date	19830313
End Marketing Date	20091003

Enter approximate end marketing date if delisting the product

- If marketing of product is discontinued, select “Completed” from the Product Status drop-down menu.
- Then enter the approximate end marketing date using the YYYYMMDD format in the “End Marketing Date” field.

Marketing Category

Marketing Category	
Marketing Category	OTC monograph not final 

- Select the appropriate marketing category for a product which is both a cosmetic and drug from the drop-down menu.

Citation Number

Add Application or citation number

Delete Application or citation number

- To add a monograph citation number, click the “Add Application or citation number” button.

Entering the citation number



The screenshot shows a web form with a light gray background. At the top, there is a label "Application or citation number" in a dark font. To its right is a text input field containing the text "part352". Below the input field, there are two buttons: "Add Application or citation number" on the left and "Delete Application or citation number" on the right. A dotted arrow points from the "Delete" button up to the input field.

Enter the citation number.

- Monograph citations include the number of the regulatory part (e.g., part234)
- List of the citation numbers (file name: otcval.xml) is included in the “Additional Validation File” zip file accessible via this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm>

Adding the Citation Number Code System

Add Application or citation number code system

Delete Application or citation number code system

- To add the citation number code system, select the “Add Application or citation number code system” button.

Selecting the Code System



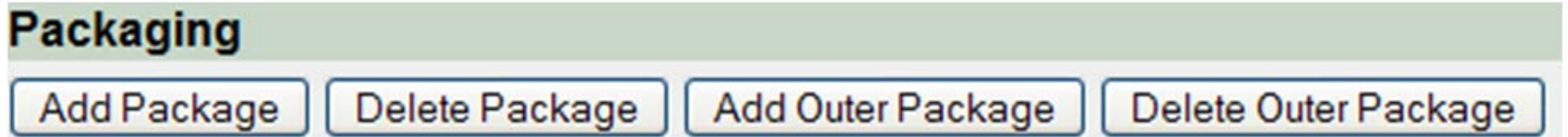
Application or citation number code system Regulatory Citation ▼

Add Application or citation number code system Delete Application or citation number code system

Select "Regulatory Citation" from the drop-down list.

- Select “Regulatory Citation” as the code system for human OTC monograph drug products.

Packaging



- Click on the “Add Package” button to add a package configuration.

Entering NDC Package Code

The diagram illustrates the structure of the NDC Package Code. It shows a form field labeled "NDC Package Code (10 digit)" containing the value "11145-123-01". A green header bar above the field is labeled "Packaging". Below the field, two callout boxes provide instructions: one for the "NDC Labeler Code (1st segment)" and another for the "NDC Product Code (1st two segments)".

Packaging

NDC Package Code (10 digit) 11145-123-01

NDC Labeler Code (1st segment) in this file should match the labeler code in the NDC Labeler Code SPL file.

NDC Product Code (1st two segments) should match NDC Product Code entered earlier in this file.

- Enter the 10 character NDC Package Code. The NDC Package Code is the NDC Product Code and the package segment of the NDC separated by a hyphen.
- NDC Labeler Code (1st segment) should match labeler code in the NDC Labeler Code SPL file.
- NDC Product Code (1st two segments) should match the NDC Product Code entered in the NDC Product Code field of same file.
- **DO NOT** use asterisks in package code field.

Entering Quantity for Packaging Description

Quantity	40	GRAM	▼
----------	----	------	---

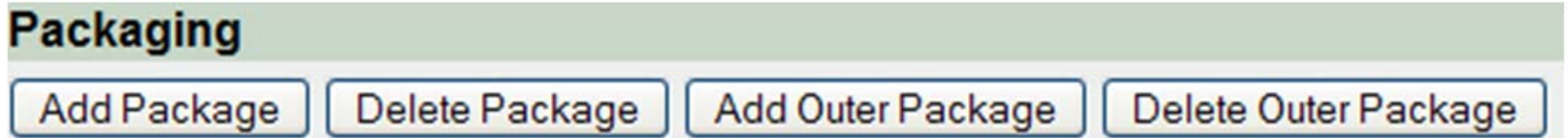
- Enter the quantity in the first field and then select the appropriate unit.
- The unit is the same as the denominator unit for the ingredient strength.
- The UCUM will be used in the strength description and the term will be used in the package description.
- Example:
 - **Strength:** “g” (“g” is the UCUM for “gram”)
 - **Package description:** “GRAM.”

Adding Package Type

Package Type 

- Select the appropriate package type.

Adding Outer Package



- Click on “Add Outer Package” button to add an outer retail package configuration and repeat the previous steps.

Example of Multi-Level Packaging

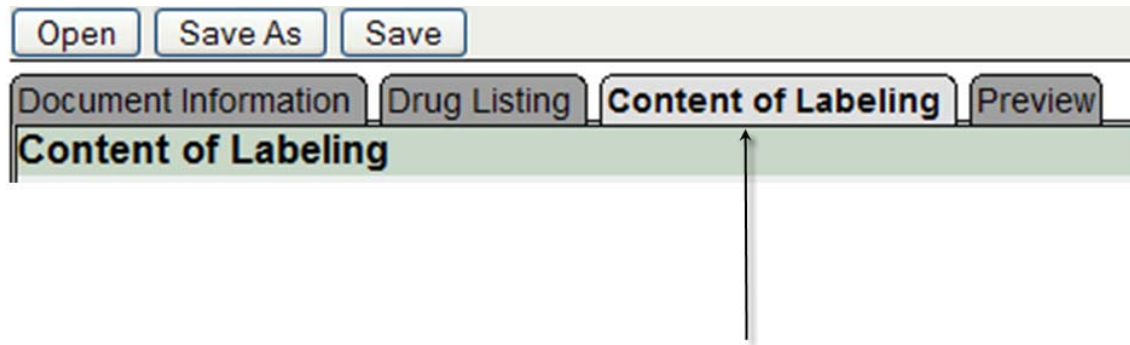
Packaging		
NDC Package Code (10 digit)	11445-123-01	
Quantity	40	GRAM
Package Type	TUBE	
NDC Package Code (10 digit)	11445-123-02	
Quantity	1	TUBE
Package Type	CARTON	

Inner level Packaging (points to the first row)

Outer Level Packaging (points to the second row)

- Note:
 - See above graphic for example of two levels of packaging with different NDC package codes (3-segment NDC)
 - If there is only one NDC for a multi-level packaged product, include the NDC on the outer level.

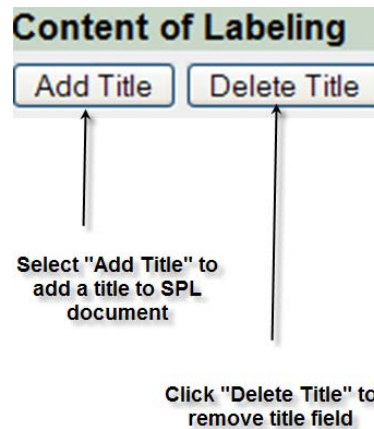
Content of Labeling for Listing SPL Document



Click the "Content of Labeling" tab to navigate to the content of labeling section of listing SPL Xforms

- Click the “Content of Labeling” tab to navigate to the content of labeling view of SPL Xforms.

Adding SPL Document Title for Listing SPL Document



- Click on the “Add title” button.
- Enter the title of the label.
- The SPL document title could be “Drug Facts” for cosmetic drug listing SPL.

Add Section



Add at least one content of labeling section

- Click the “Add Section” to add the section.

Choose Section Header

Section	OTC - ACTIVE INGREDIENT SECTION	▼
---------	---------------------------------	---

- Choose applicable section header from drop-down menu.

Hyperlink ID



- **IGNORE** “Hyperlink” buttons for listing SPL documents for products which are both a cosmetic and drug.

Enter Section ID

ID

62675ee0-e6f7-4488-8947-39e1d57fbb04

- Enter a GUID for the section ID.

Adding Section Title



- Enter a section title, if necessary.
- If no section title, do not click “Add Title.”
- Use “Delete Title” if “Add Title” is selected in error.

Section's Effective Time (Date)

Effective Time	20090626
----------------	----------

- Enter a time stamp (effective time) for the content of labeling section
- Ensure that there are no spaces (created w/space bar) before or after date.
- The effective time provides a date reference for the section.
- The date includes the year, month and day using the format `yyyymmdd`.

Highlights Feature



- **IGNORE** the highlights buttons for listing SPL documents for products which are both a cosmetic and drug.

Entering Section Text



Select "Edit" button to
display section text field.

- Click the “Edit” button to display the section text field.

Entering Text and Using “Widgets”



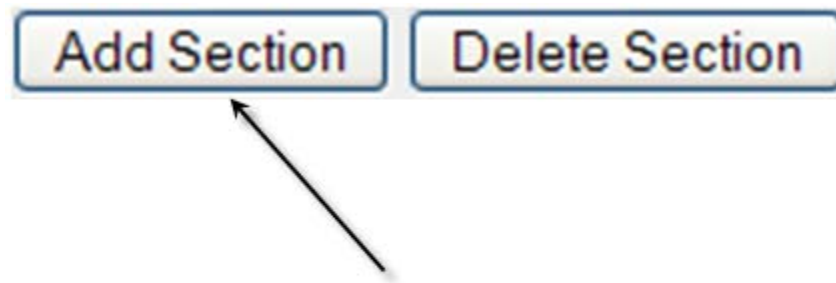
- Enter text from a section of the content of labeling (Drug Facts.)
- Type or copy/paste text into section field.
- Use “widgets” to alter the font (bold, italics), etc...

Saving the Section



- Click the “Save” button to save the section text just entered.

Adding More Content of Labeling Sections



Click "Add Section" button to add a section.

- Follow the instructions in the previous pages related to content of labeling to create another section.
- Continue to add sections until each section or subsection in the content of labeling is represented in a separate SPL content of labeling section or sub-section.

Adding Sub-sections



- Click “Add Sub-Section” button to add a sub-section, if applicable.

Creating the Sub-Section

The screenshot shows a web form for creating a sub-section. It includes a dropdown menu for the section header, a text input for the section ID, a text input for the title, and a text input for the sub-section text. Callout boxes provide instructions: 'Add a section header and a section ID' points to the dropdown and ID input; 'Add sub-section title' points to the title input; and 'After selecting "Edit" button, enter text for sub-section.' points to the sub-section text input and the 'Edit' button.

Section ID	Title
OTC - ASK DOCTOR SECTION	997ac49b-a19a-4763-9d10-41c2434fe2ee
Ask Doctor	

Sub-section Text

Enter section text here

Edit

- Follow steps used to create the content of labeling section, except this time, create a subsection.
- See graphic above for more details.

Principal Display Panel Section

Section	PACKAGE LABEL.PRINCIPAL DISPLAY PANEL	▼
---------	---------------------------------------	---

- Add a section (not sub-section.)
- Choose Package.Label Principal Display Panel section header from “Section” drop-down menu.
- Listing SPL document for a product which is both a cosmetic and drug **should** have a “Package Label.Principal Display Panel” section header.
- Include image of carton/container label in this section.

Referencing the Images Using “Add Media” Button

Content of Labeling

Add Title Delete Title

Section PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Add Hyperlink ID Delete Hyperlink ID

ID 276c2bdb-411e-4373-9766-dae2da1a0c5a

Add Title Delete Title

Add Effective time Delete Effective time

Add Highlight Delete Highlight

Section Text

Place holder text

Edit

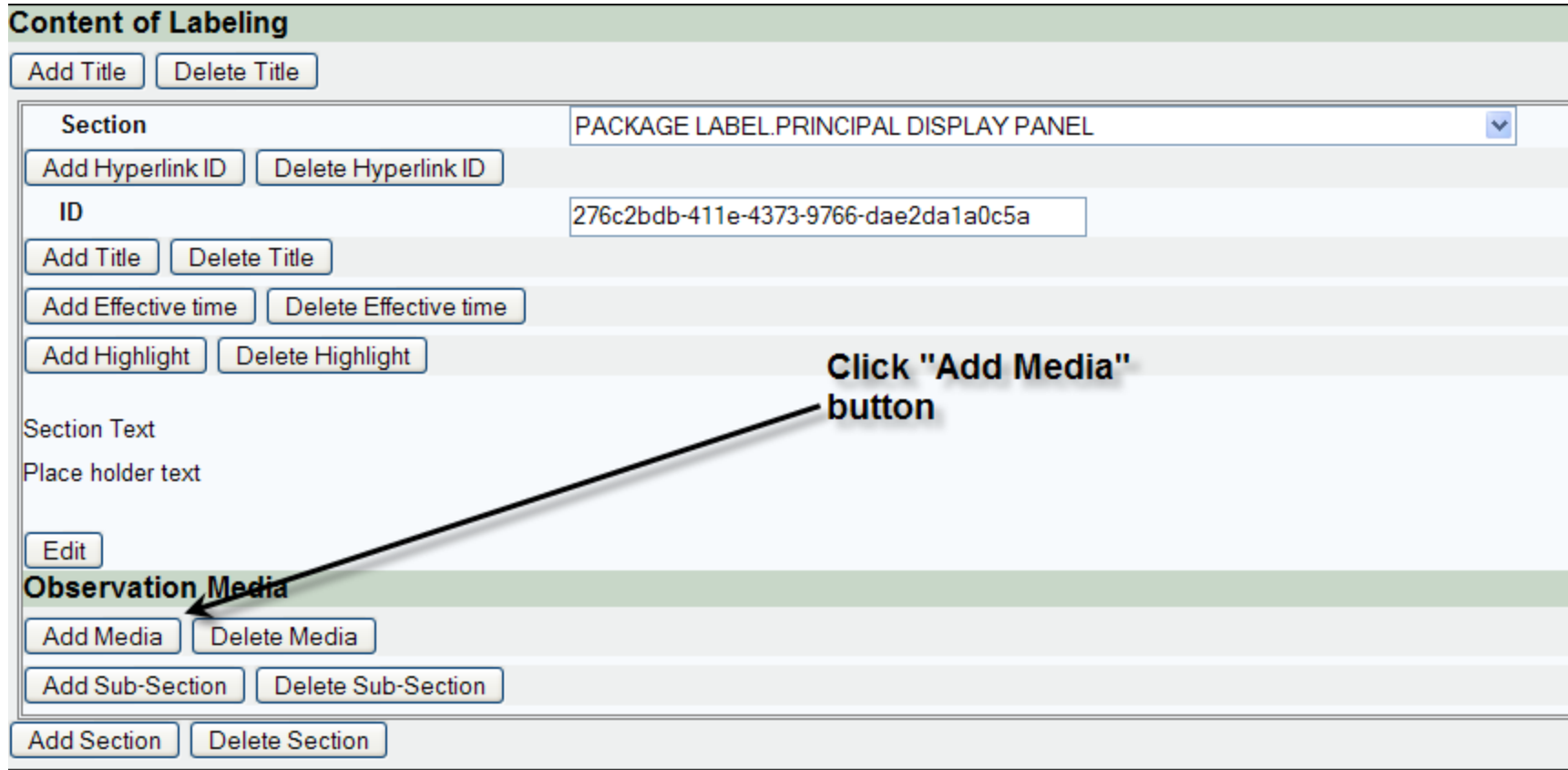
Observation Media

Add Media Delete Media

Add Sub-Section Delete Sub-Section

Add Section Delete Section

Click "Add Media" button



Entering ID, Descriptive Text & File Name

1. Enter an ID (e.g. "MM1" or "MM2" - each image ID should be unique)
2. Add descriptive text for image
3. Enter image file name

Section Text

Place holder text

Edit

Observation Media

ID	MM1
Descriptive Text	image of carton label
File Name	carton.jpg

Selecting Location of Image

Section Text

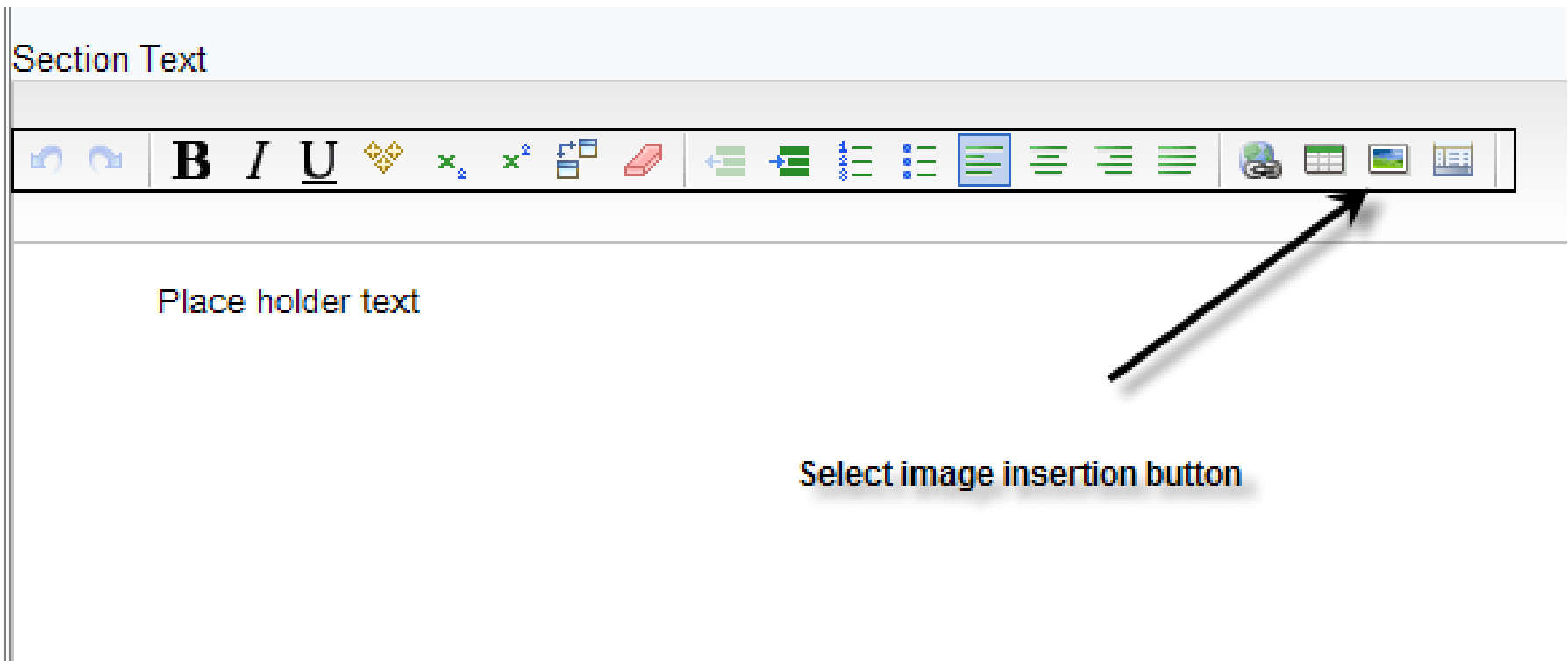


Place holder text

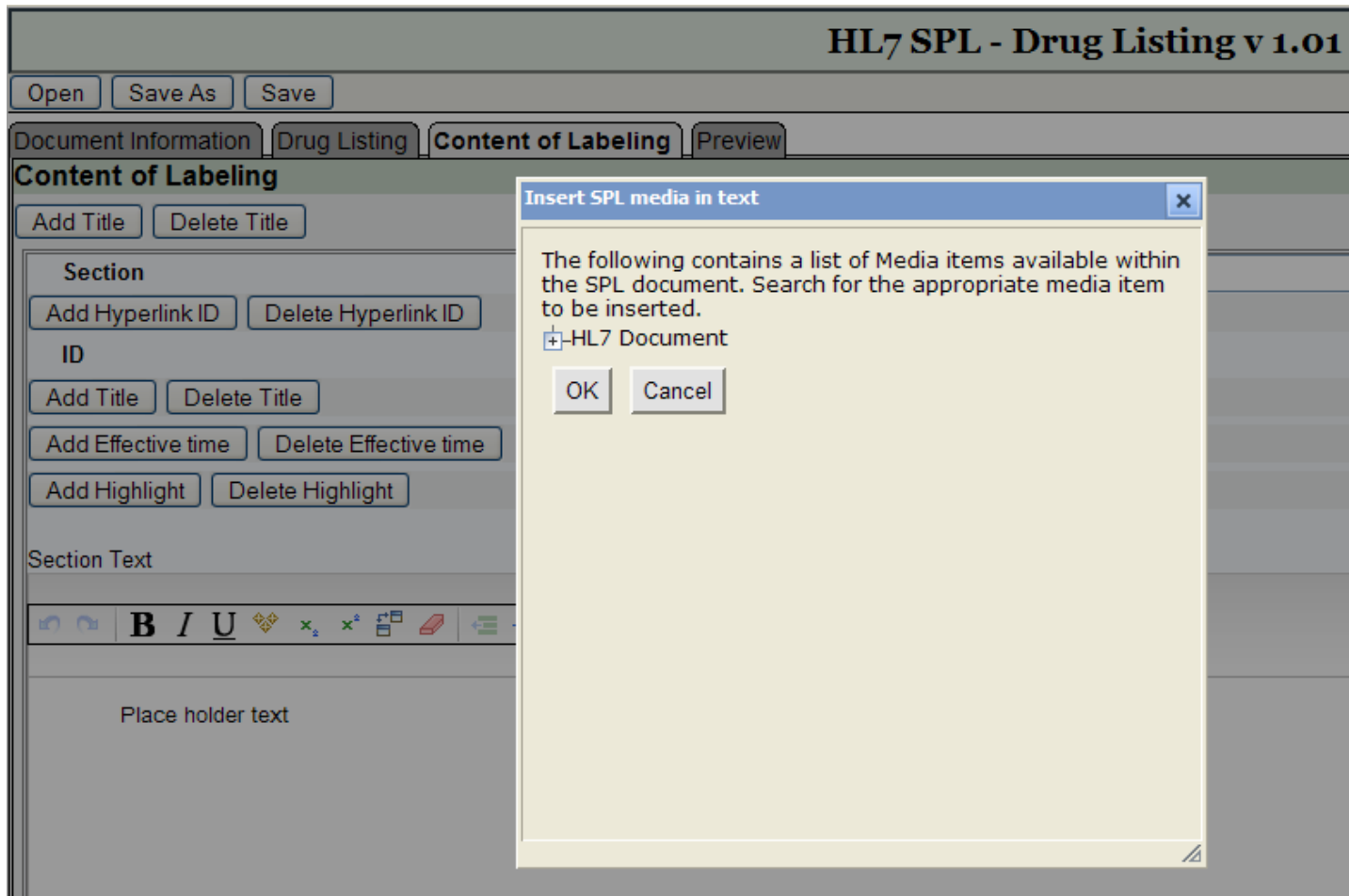


Place the computer cursor in the location where image should appear

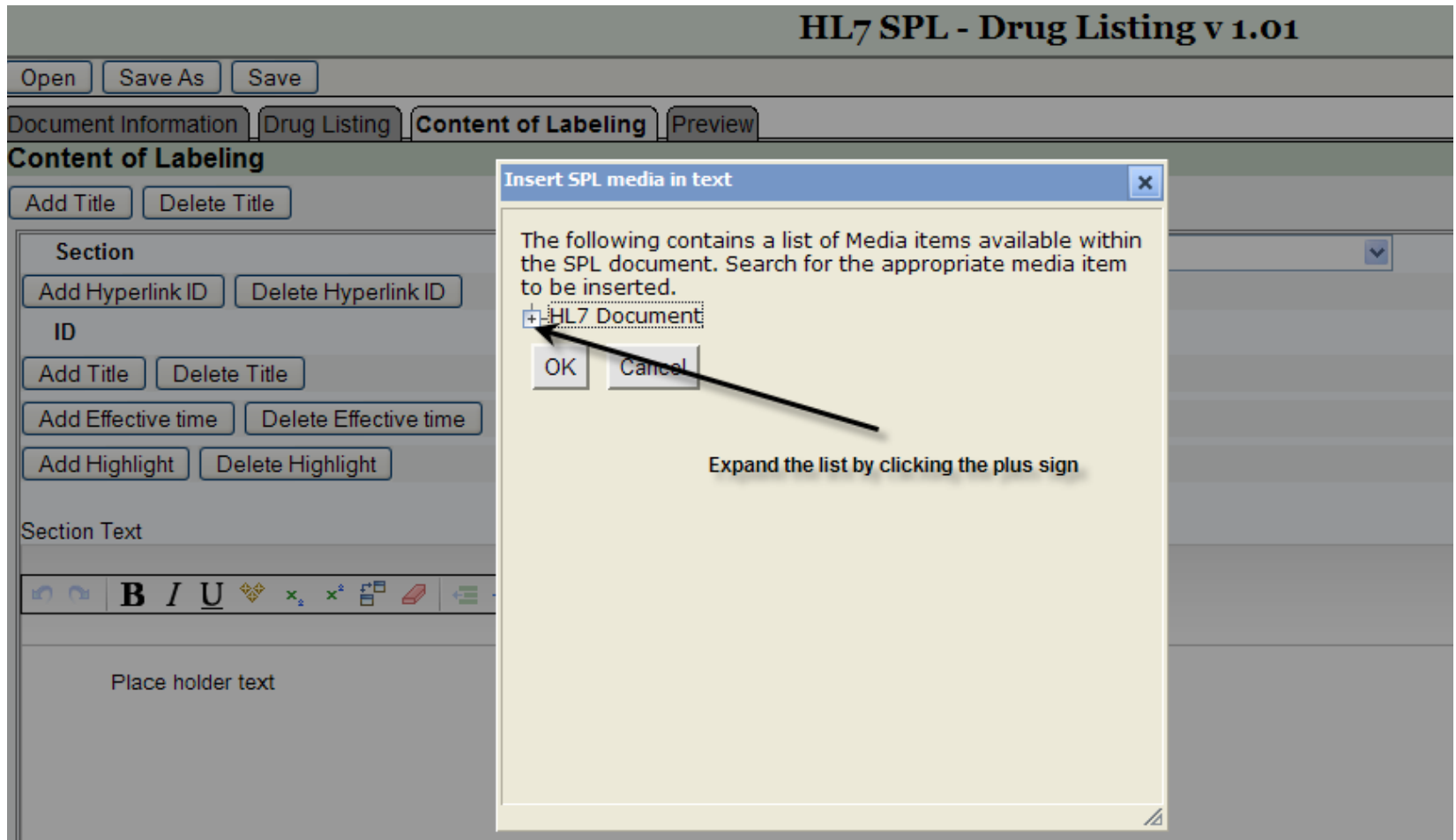
Selecting Image Insertion Button



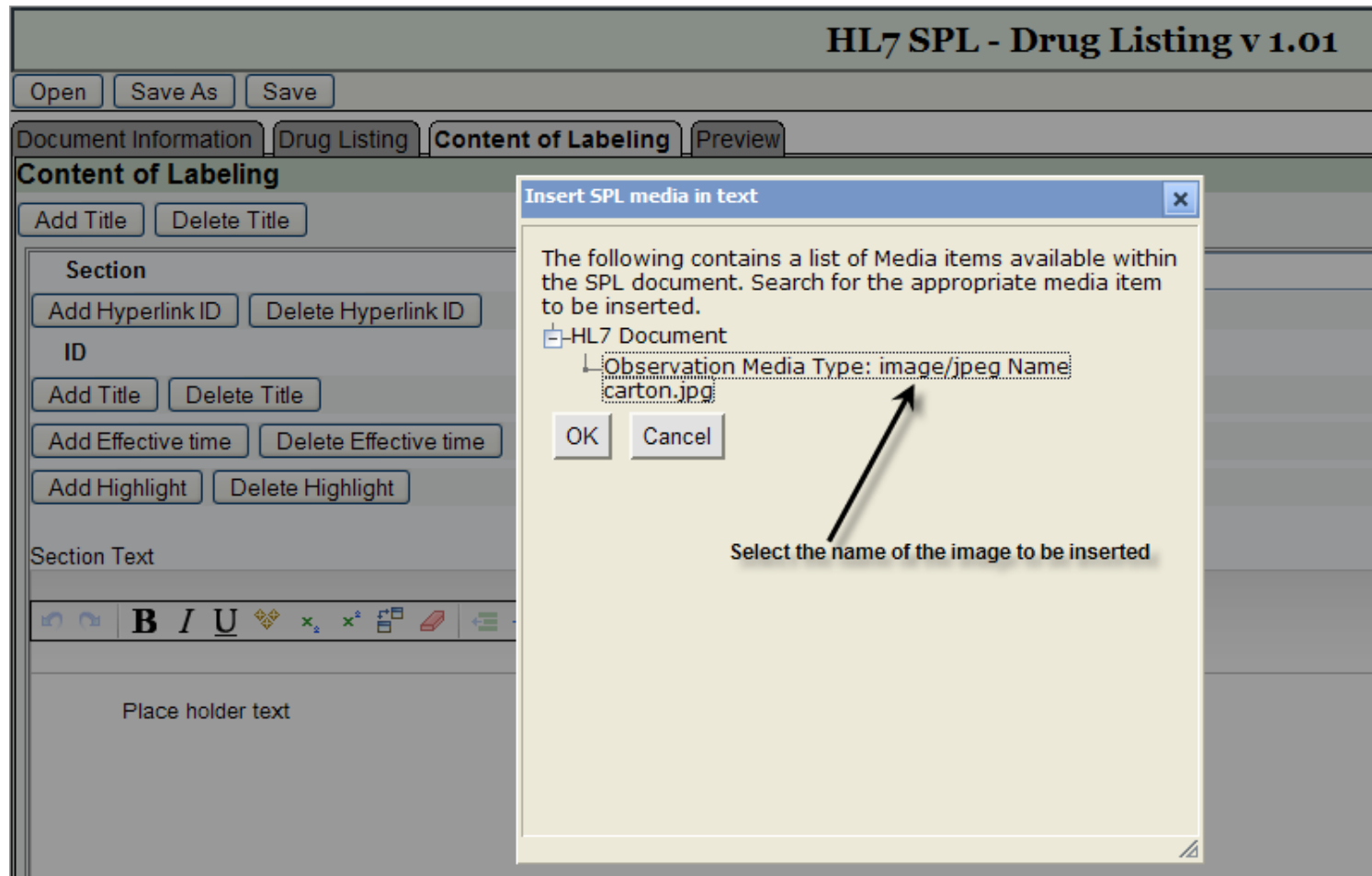
Insert Media Prompt Box



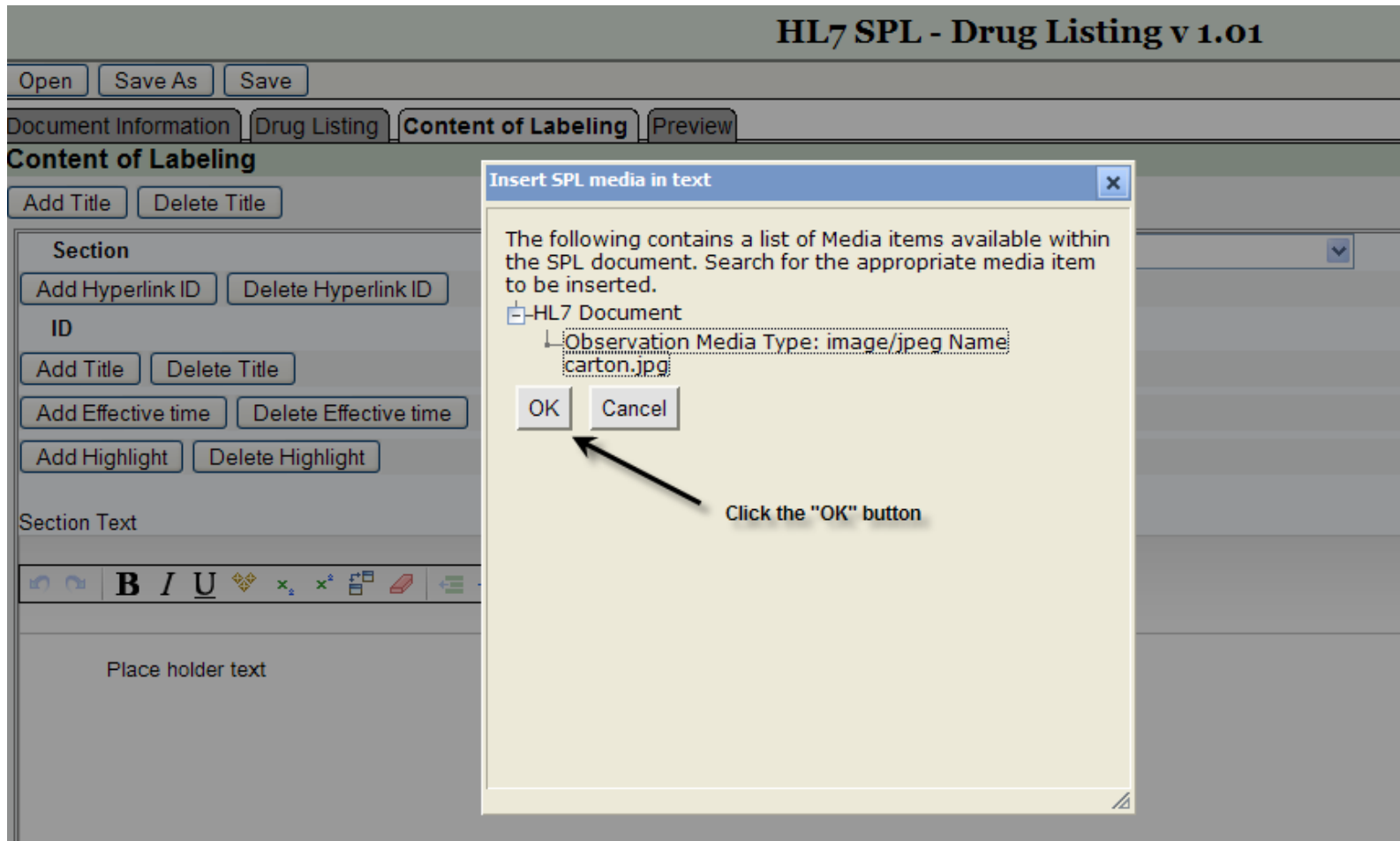
Expanding Image List



Selecting Image to Insert



Finish Image Selection



Verifying Image Insertion

Section Text



Place holder text



An image placeholder icon will appear (image will not render in SPL Xforms)

Saving Section w/Image

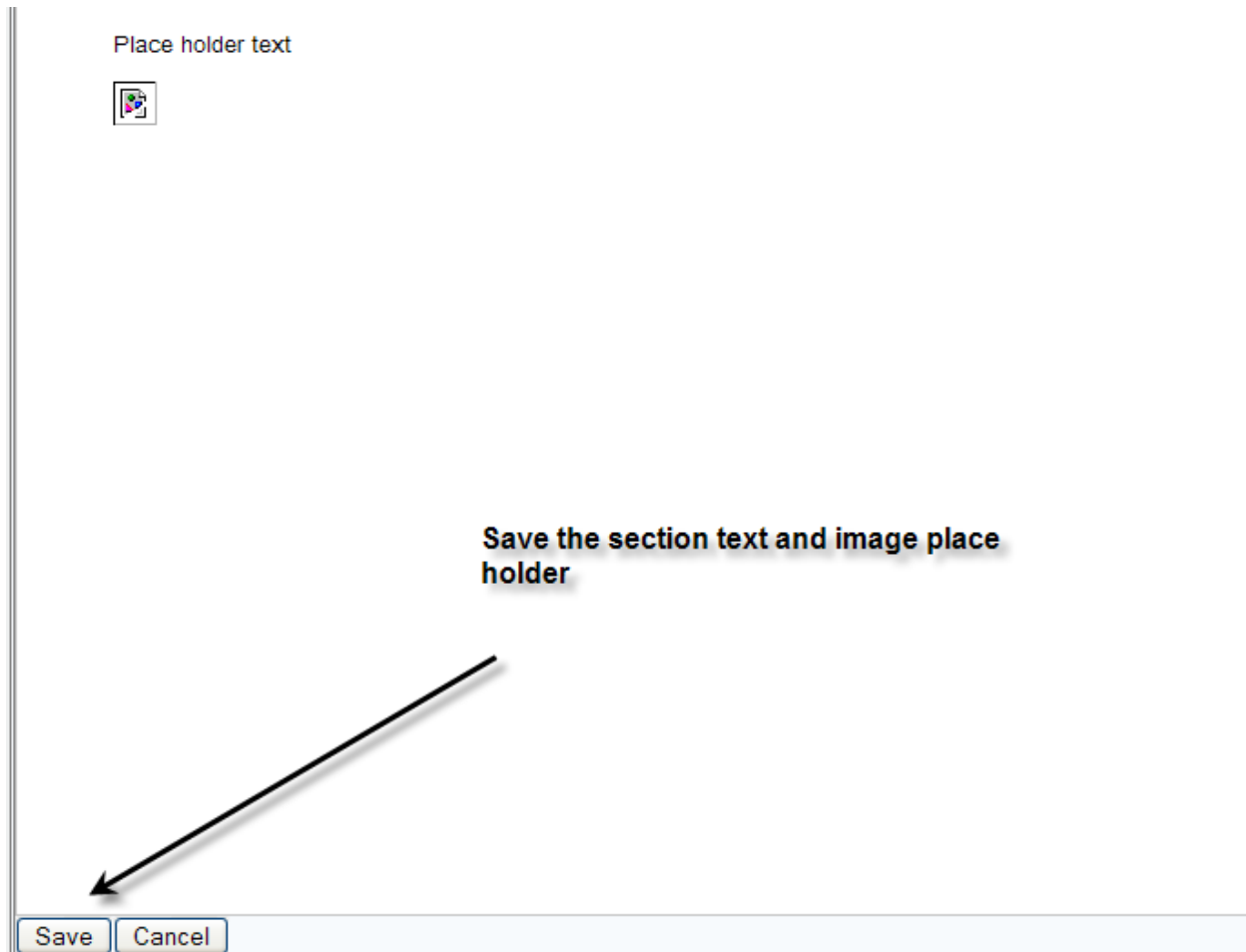
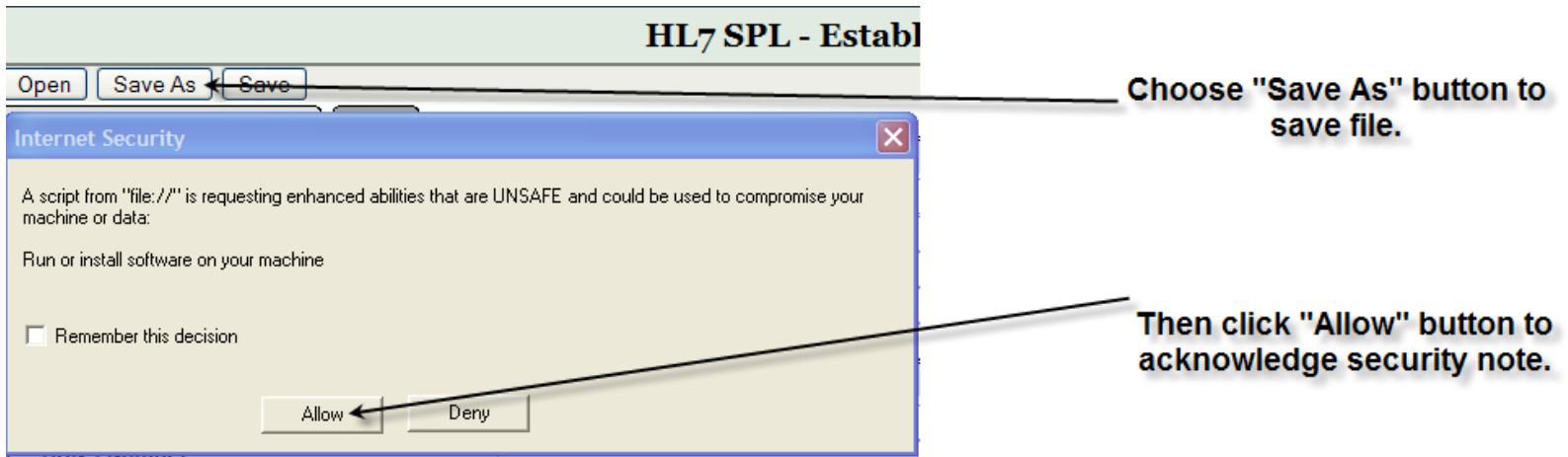


Image Notes

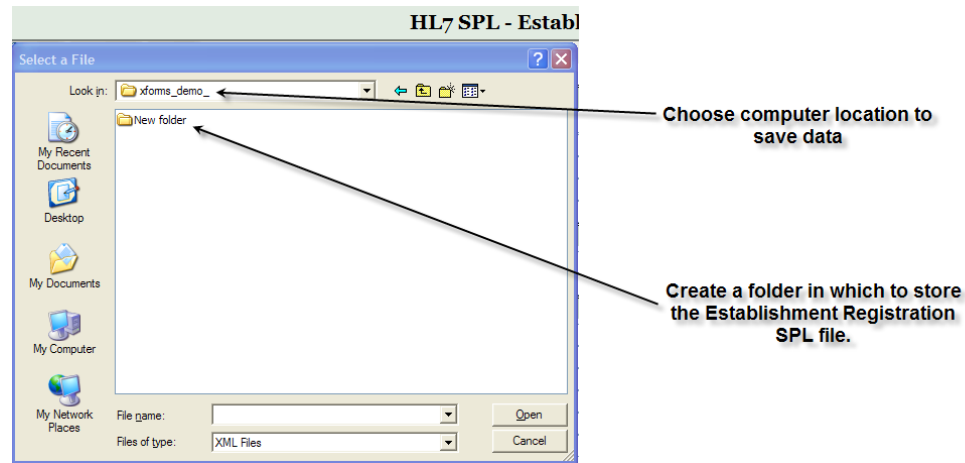
- Image should be viewable in window without scrolling.
- Size of image file should be under **1 MB**.

Saving the File



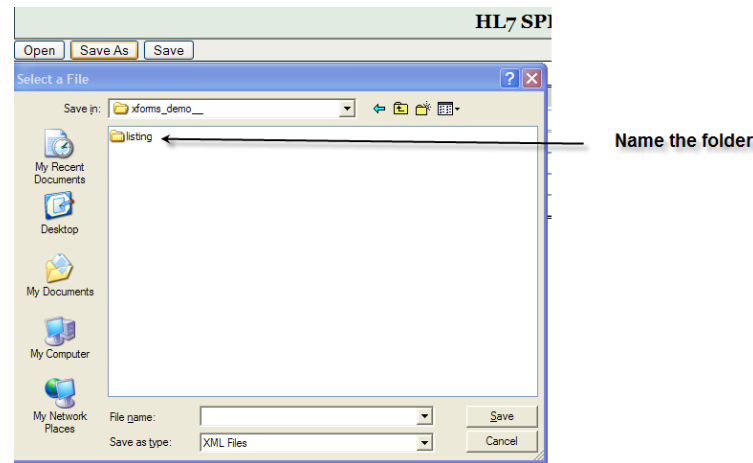
- When saving the SPL file for the first time, select the “Save As” button.
- Then select the “Allow” button to continue saving.
- You can check “Remember This Decision” checkbox to avoid future security prompts.

Creating the Submission Folder



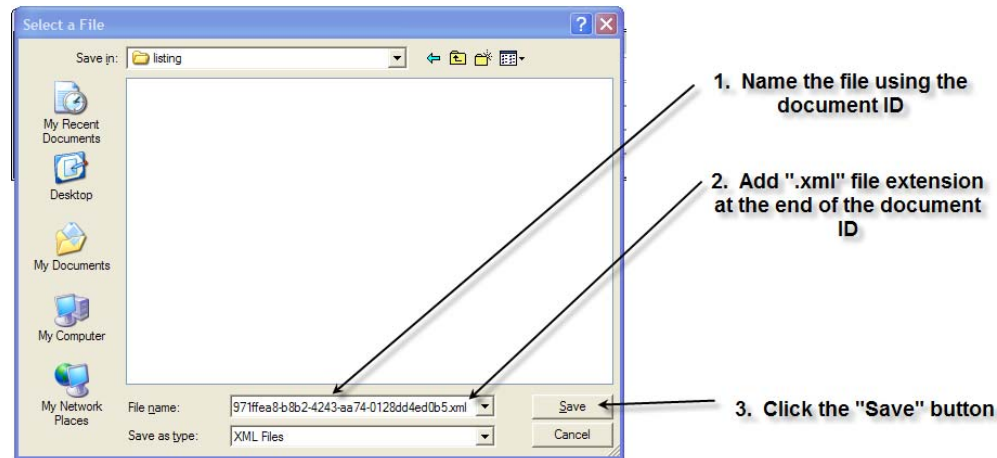
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the listing SPL file.

Naming the Submission Folder



- There is no folder naming convention
- However, we recommend that you not use symbols in the name of the folder.

Naming the SPL File



- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

Need More Detailed Instructions?

- Use Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for Drug Establishment Registration and Drug Listing
- This document is located on the SPL Resources web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
 - This validator tool is **NOT** connected to FDA database.
 - This tool assist you in detection of 90 – 95% of technical errors in SPL documents.

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph about the council's role and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards
Validators
Data Council
Structured Product Labeling
Individual Case Safety Reports
Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)